

## **REMARKS**

### **Request for Extension of Time**

Applicants, through their undersigned attorney, respectfully request a two-month extension of time for responding to the Communication mailed 8 February 2007 in the above-identified patent application. The time for response is thus extended up to and including 8 July 2007.

The amendments set out above and the following remarks are believed responsive to the points raised by the Examiner in the Office Action dated 2 February 2007. Entry of the above is respectfully requested.

Following the entry of this amendment claims 1, 2, 5, and 8 are pending. In view of the amendments set out above and the following remarks, reconsideration is respectfully requested.

Please note that the Office Action indicates that claim 5 is withdrawn and that claim 4 is pending. In the previous response, Applicant elected the 4B6 species, so claim 5 should be pending and claim 4 should have been withdrawn. This is reflected in the claim set above, and in the rejections below, claim 5 has replaced claim 4 as was believed intended in the office action.

The following comments address the points raised by the Examiner in the order they are presented in the Official Action.

### **Priority**

In paragraphs 2 and 3, the office action indicates that the present application is not entitled to priority of U.S. provisional application 60/440,326 (filed 16 January 2003) because the inventorship is different. Applicant respectfully requests reconsideration.

The inventorship of the present application is correct and the inventorship of the provisional application is incorrect; Dr. Marvin Fritzler is properly named as the sole inventor in the present application. Applicant, through his undersigned attorney, has filed a separate Petition to Correct Inventorship under 37 CFR 1.48 (e) to correct the inventorship of the provisional application.

Applicant shall approach the present response under the assumption that Applicant's Petition to Correct Inventorship shall be approved by the Commissioner.

Applicant respectfully requests reconsideration of Applicant's request for priority.

Concerning the 35 U.S.C. 112, First Paragraph rejection of Claims 2 and 5

Claims 2 and 5 have been rejected for lacking enablement and/or adequate written description for failure of the specification to provide proper indication that the biological material has been deposited. Applicant respectfully requests reconsideration.

The undersigned attorney of record hereby states that all four of the monoclonal antibodies noted in all of the claims have been deposited under the Budapest Treaty, that the cell lines will be irrevocably and without restriction or condition released to the public upon issuance of a patent, and that the cell line(s) will be replaced should they ever become unviable. Independent evidence of the deposit is attached in the form of a Statement of Viability for each of the deposited four monoclonal antibodies. Accession Number 130204-12 corresponds to MAb 4B6; Accession Number 130204-13 corresponds to MAb 2D6; Accession Number 130204-14 corresponds to MAb 5C6; and Accession Number 130204-15 corresponds to MAb 6D7.

Applicant has amended the specification in order to comply with 37 CFR §§ 1.801-1.809.

Thus, in light of the foregoing amendment and remarks, Applicants submit that the rejection has been overcome. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, first paragraph rejection of claims 2 and 5.

Concerning the 35 U.S.C. 112, Second Paragraph rejection of Claims 2, 5, and 8

Claims 2, 5, and 8 have been rejected as being indefinite for specific reasons noted in the office action. In order to address the issues raised in the office action, the claims have been amended as follows: Claim 2 has been amended to remove the references to non-elected species; the deposit information (an accession number) has been added to claim 5; and the suggestion for the amendment to claim has been adopted.

Regarding claim 8 and the "assaying" step, Applicant has changed "assaying for" to "detecting" so that the preamble and the last step match. However, it is not understood what might be vague about assaying for the presence of bound antibody. The use of monoclonal antibodies, a wide variety of antibody detection techniques, and a wide variety of antibody assay techniques are very old in the art. For example, the USPTO's Written Description Guidelines describe antibodies as a "mature" art. Applicant is not using the words or intending the definition to exceed what is exceedingly well known to one of ordinary skill in the art. For example, immunoassays, radioimmunoassay, fluorescence assays, to name just a few, are all well known and well characterized assays for detecting the presence of an antibody. Applicant therefore respectfully submits that this aspect of the claimed invention is not vague, but is actually quite well understood.

Thus, in light of the foregoing remarks, Applicants submit that the rejection has been overcome. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, second paragraph rejection of claims 2, 45 and 8.

Concerning the 35 U.S.C. 102(f) rejection of Claims 1, 2, 5, and 8

Claims 1, 2, 5, and 8 have been rejected under 35 U.S.C. 102(f) on the basis that the inventor did not invent the claimed subject matter. Reconsideration is respectfully requested.

The office action cites Eystathioy et al., (*Hybridoma and Hybridomics*, 22:79-86 (2003)) and indicates that the inventorship in the present application is different than the authorship for the cited publication.

The cited publication describes the invention in part, but was published after the filing date of applicant's priority document, U.S. provisional application no. 60/440,326 (filed 16 January 2003). Applicant is an author listed on the publication, but he is the sole inventor of the claimed invention. The other authors worked at his direction and did not invent any of the claimed subject matter, so they are not properly named as inventors.

As evidence, Applicant submits a Rule 132 Declaration affirming that the other authors on the cited publication are not inventors.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 102(f) rejection of claims 1, 2, 5, and 8.

Concerning the 35 U.S.C. 102(a) rejection of Claims 1, 2, 5, and 8

Claims 1, 2, 5, and 8 have been rejected under 35 U.S.C. 102(a) as being anticipated by Eystathioy et al., cited above. Reconsideration is respectfully requested.

As noted above, with the correction of the inventorship of applicant's priority document, U.S. provisional application no. 60/440,326 (filed 16 January 2003), the present application claims priority of an application that was filed prior to the publication date of the

cited publication. Applicant has filed a Petition to the Commissioner to correct the inventorship of the provisional application, and when that Petition is granted, the priority of the present application will be prior to the cited reference, therefore making this rejection inappropriate.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 102(a) rejection of claims 1, 2, 5, and 8.

35 U.S.C. 103(a) rejection over Eystathioy in view of Kohler

The Official Action rejected claims 1 and 8 under 35 U.S.C. ' 103(a) as unpatentable over Eystathioy et al., cited above, and Kohler (*Science*, 233:1281-1286 (1986)). Reconsideration is respectfully requested.

For the reasons noted above, Eystathioy et al is not available as a reference against the claims of the present invention because the reference was published after the filing date of applicant's priority document. As such, this publication can not provide prima facie support for a section 103 rejection.

Accordingly, Applicants respectfully request reconsideration of the rejection of claim 1 and 8 and withdrawal of the 35 U.S.C. 103(a) rejection.

Accordingly, in view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney at 410-923-2660.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 02-4650.

Respectfully submitted,

/wjbundren/

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William J. Bundren  
PTO Reg. No. 31,712

734 Larue Road  
Millersville, Maryland 21108-2155

Telephone: 410-923-2660  
Facsimile: 410-923-2478